**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**WACO DIVISION**

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| Ravgen, Inc.,<br><br>Plaintiff,<br><br>v.<br><br>PerkinElmer, Inc., PerkinElmer Genetics, Inc., and Bioo Scientific Corporation,<br><br>Defendants. | Civil Action No. 6:20-cv-452<br><br>**JURY TRIAL DEMANDED** |

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Ravgen, Inc. ("Ravgen"), for its Complaint against Defendants PerkinElmer, Inc., PerkinElmer Genetics, Inc., and Bioo Scientific Corporation ("Defendants"), hereby alleges as follows:

## NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 7,727,720 (the "'720 Patent") and 7,332,277 (the "'277 Patent") (collectively the "Patents-in-Suit"), arising under the Patent Laws of the United States, 35 U.S.C. §§ 271, *et seq*.

## THE PARTIES

2. Plaintiff Ravgen is a Delaware corporation with its principal place of business at 9241 Rumsey Rd., Columbia, MD 21045. Ravgen is a pioneering diagnostics company that focuses on non-invasive prenatal testing. Ravgen has spent millions of dollars researching and developing novel methods for the detection of cell-free DNA to replace conventional, invasive procedures. Ravgen's innovative cell-free DNA technology has various applications, including

non-invasive prenatal and other genetic testing. Those efforts have resulted in the issuance of several patents, including the Patents-in-Suit.

3. Defendant PerkinElmer, Inc. is a Massachusetts corporation with its principal place of business at 940 Winter Street, Waltham, MA 02451. PerkinElmer, Inc. is registered to do business in the state of Texas. (Ex. 7 at 1 (Texas Secretary of State report for PerkinElmer, Inc.).) PerkinElmer, Inc. has appointed C T Corporation System, 1999 Bryan St., Ste. 900 Dallas, TX 75201 as its agent for service of process. (*Id.*) PerkinElmer, Inc. operates and maintains facilities at 7050 Burleson Road, Austin, TX 78744. (*See, e.g.*, Ex. 11 (product documentation for "NextPrep-Mag™ cfDNA Automated Isolation Kit," available at https://perkinelmer-appliedgenomics.com/wp-content/uploads/marketing/NextPrep/3825-05-and-3825-06-NextPrep-Mag-cfDNA-Automated-Isolation-Kit_v18.07.pdf) (listing address "7050 Burleson Road, Austin, Texas 78744"); Ex. 12 (product documentation for "NEXTflex® Rapid DNA-Seq Kit 2.0," available at https://c2x9r4v3.stackpathcdn.com/wp-content/uploads/2019/12/NOVA-5188-01-NEXTflex-Rapid-DNA-Seq-kit-2.0_v19.12_v5.pdf) (listing address "7050 Burleson Road, Austin, Texas 78744"); Ex. 13 (http://www.biooscientific.com/How-to-Order) (providing "Ordering from PerkinElmer" instruction with mailing address of "PerkinElmer, 7050 Burleson Rd, Austin, TX 78744, USA"; also providing order form (attached as Ex. 14 (available at http://www.biooscientific.com/Portals/0/Images/Bioo_Scientific_Order_Form_2017_72-02_REV_F.pdf)) with mailing address: "PerkinElmer, 7050 Burleson Rd., Austin, TX 78744"); Ex. 60 at 1 ("Contact Us" webpage, available at https://perkinelmer-appliedgenomics.com/home/contact-us/) (providing "7050 Burleson Road. Austin, Texas 78744" as address for PerkinElmer, Inc.).)

4. PerkinElmer, Inc., itself and/or through its subsidiaries, makes, uses, and commercializes genetic tests using cell-free DNA. For example, PerkinElmer, Inc., itself and/or through its subsidiaries, makes, uses, and commercializes the Vanadis® NIPT Assay, a test for the detection of chromosomal abnormalities using cell-free fetal DNA. For example, PerkinElmer, Inc., itself and/or through its subsidiaries, makes, uses, and commercializes kits for the extraction, processing, and detection of cell-free DNA, including the chemagic™ cfDNA 5k Kits, the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits (collectively, the "cfDNA Kits").

5. PerkinElmer, Inc., itself and/or through its subsidiaries, markets, offers for sale, sells, and distributes the Vanadis® NIPT Assay and the cfDNA Kits throughout the United States and in this District, including through its websites, www.PerkinElmer.com, www.PerkinElmerGenomics.com, www.PerkinElmer-AppliedGenomics.com, www.chemagen.com, and www.BiooScientific.com. (*See, e.g.,* Ex. 17 (https://prenataltesting.perkinelmer.com/products/vanadis_nipt_system); Ex. 18 (https://www.perkinelmergenomics.com/healthcare-providers/Vanadis-NIPT/index.html); Ex. 19 (https://perkinelmer-appliedgenomics.com/home/products/library-preparation-kits/dna-library-prep-kits/nextflex-rapid-dna-seq-2-0/); Ex. 20 (https://perkinelmer-appliedgenomics.com/home/products/cfdna-cfrna-isolation/nextprep-mag-cfdna-automated-isolation-kit/); Ex. 21 (http://shop.biooscientific.com/nextprep-mag-cfdna-automated-isolation-kit/); Ex. 22 (https://chemagen.com/wp-content/uploads/2018/10/cfDNA_Isolation_Kit_Automation.pdf); Ex. 23 (http://shop.biooscientific.com/nextflex-cell-free-dna-seq-kit/); Ex. 24 (https://chemagen.com/Kits/chemagic-cfdna5k-kit-h24/).)

6. Additionally, PerkinElmer, Inc., itself and/or through its subsidiaries, uses the Vanadis® NIPT Assay to process samples at its laboratory facilities. (Ex. 25 (https://www.businesswire.com/news/home/20191029005643/en/PerkinElmer-Genomics%E2%80%99-Clinical-Labs-U.S.-Malaysia-Process); Ex. 26 ("Prenatal and Reproductive Test Requisition Form," available at https://www.perkinelmergenomics.com/Images/Prenatal_Reproductive_TRF_tcm206-222160.pdf).)

7. Defendant Bioo Scientific Corporation is a Texas corporation with its principal place of business at 7050 Burleson Road, Austin, TX 78744. (Ex. 61 at 1-2 (Bioo Scientific "Contact Us," available at http://www.biooscientific.com/Contact-Us) (listing "7050 Burleson Road, Austin, TX 78744" as the "Contact Us" address and as the address for "Austin, TX, USA, HQ"); Ex. 62 at 1-2 (Bioo Scientific LinkedIn page, available at https://www.linkedin.com/company/bioo-scientific/about/) (explaining that "Bioo Scientific Corporation is an Austin, TX based biotechnology company," listing "Austin, TX" as the location of the "Headquarters," and listing "7050 Burleson Rd, Austin, TX 78744, US" as the company's "Primary" location).) Bioo Scientific Corporation is registered to do business in Texas and may be served through its registered agent for service, C T Corporation System, 1999 Bryan St., Ste. 900 Dallas, TX 75201. (Ex. 8 at 1 (Texas Secretary of State report for Bioo Scientific Corporation).) Bioo Scientific Corporation is a wholly-owned subsidiary of PerkinElmer Holdings, Inc., which is a wholly-owned subsidiary of PerkinElmer, Inc. On information and belief, PerkinElmer, Inc. directs the activities of or exercises control over Bioo Scientific Corporation through PerkinElmer Holdings, Inc., including its activities in this District.

8. Bioo Scientific Corporation makes, uses, and commercializes kits for genetic testing using cell-free DNA, including the NextPrep-Mag™ cfDNA Automated Isolation Kit and NEXTflex® Cell-Free DNA-Seq Kit. Bioo Scientific Corporation markets, offers for sale, sells, and distributes those products throughout the United States and in this District, including through its website, www.BiooScientific.com. (*See, e.g.*, Ex. 21 (Bioo Scientific Corporation website advertising for sale "NextPrep-Mag™ cfDNA Automated Isolation Kit"); Ex. 23 (Bioo Scientific Corporation website advertising for sale "NEXTflex® Cell Free DNA-Seq Kit").)

9. Defendant PerkinElmer Genetics, Inc. is a Pennsylvania corporation with its principal place of business at 250 Industry Drive, Suite 400, Pittsburgh, PA 15275. PerkinElmer Genetics, Inc. is registered to do business in Texas and may be served through its registered agent for service, C T Corporation System, 1999 Bryan St., Ste. 900 Dallas, TX 75201. (Ex. 10 at 1 (Texas Secretary of State report for PerkinElmer Genetics, Inc.).) PerkinElmer Genetics, Inc. is a wholly-owned subsidiary of PerkinElmer Diagnostics Holdings, Inc., a wholly-owned subsidiary of PerkinElmer Holdings, Inc., which is a wholly-owned subsidiary of PerkinElmer, Inc. On information and belief, PerkinElmer, Inc. directs the activities of or exercises control over PerkinElmer Genetics, Inc., including its activities in this District.

10. PerkinElmer Genetics, Inc. makes, uses, and commercializes genetic tests using cell-free DNA, including the Vanadis® NIPT Assay. PerkinElmer Genetics, Inc. markets, offers for sale, sells, and distributes the Vanadis® NIPT Assay throughout the United States and in this District, including through its website, www.PerkinElmerGenomics.com. (*See* Ex. 18 (https://www.perkinelmergenomics.com/healthcare-providers/Vanadis-NIPT/index.html).) Additionally, PerkinElmer Genetics, Inc. uses the Vanadis® NIPT Assay to process samples at its laboratory facilities. (Ex. 25 ("PerkinElmer Genomics' Clinical Labs in U.S. and Malaysia to

Process Samples with Vanadis Fully Automated NIPT Platform"); Ex. 26 ("Prenatal and Reproductive Test Requisition Form," available at https://www.perkinelmergenomics.com/Images/Prenatal_Reproductive_TRF_tcm206-222160.pdf).)

**JURISDICTION AND VENUE**

11. Ravgen incorporates by reference paragraphs 1-10.

12. This action arises under the patent laws of the United States, including 35 U.S.C. §§ 271, *et seq*. The jurisdiction of this Court over the subject matter of this action is proper under 28 U.S.C. §§ 1331 and 1338(a).

13. Venue is proper in this District pursuant to U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Defendants have a permanent and continuous presence in, have committed acts of infringement in, and maintain regular and established places of businesses in this District.

14. Venue is also proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Bioo Scientific Corporation resides in the Western District of Texas for purposes of venue under 28 U.S.C. §1400(b). Bioo Scientific Corporation is incorporated in Texas and maintains its principal place of business in the Western District of Texas at 7050 Burleson Road, Austin, TX 78744.

15. By registering to conduct business in Texas and by having facilities where they regularly conduct business in this District, Defendants have a permanent and continuous presence and regular and established places of business in the Western District of Texas.

16. PerkinElmer, Inc. and Bioo Scientific Corporation maintain regular places of business in this District, including facilities at 7050 Burleson Road, Austin, TX 78744. (*See, e.g.*, Ex. 27 ("Certificate of Registration of Quality Management System," available at

http://www.biooscientific.com/Portals/0/PDF/19-8127-PerkinElmer-Inc-ISO-9001-2015-Certificate-11-14-19.pdf) (issued to: "PerkinElmer, Inc. 7050 Burleson Rd Austin, TX 78744 USA").) On information and belief, Defendants use those facilities to make, use, and support the sale of genetic testing technologies for extracting and detecting cell-free DNA, at least including the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits. (Ex. 11 (product documentation for NextPrep-Mag™ cfDNA Automated Isolation Kit) (listing address "7050 Burleson Road, Austin, Texas 78744"); Ex. 12 (product documentation for NEXTflex® Rapid DNA-Seq Kit 2.0) (same); Ex. 13 ("Ordering from PerkinElmer" instruction with mailing address of "PerkinElmer, 7050 Burleson Rd, Austin, TX 78744, USA"; also providing order form (attached as Ex. 14) with mailing address: "PerkinElmer, 7050 Burleson Rd., Austin, TX 78744").)

17. Defendants have numerous employees in the judicial district, including employees with responsibilities relating to the accused genetic testing products. For example, PerkinElmer, Inc. currently employs several individuals in Austin, Texas, including a lab technologist and a quality engineer. (*See, e.g.,* Ex. 28 at 1 (https://www.linkedin.com/in/lunawilson/); Ex. 29 at 1 (https://www.linkedin.com/in/kevin-lendian-0a4515178/).) Additionally, PerkinElmer, Inc. lists job openings on the www.perkinelmer.com website for its Austin location(s), including "Associate Lab Technologist" and "General Manager, Next Generation Sequencing." The "Associate Lab Technologist" job listing seeks a "candidate who will work as part of the production team to manufacture Next-Gen Sequencing library kits." (Ex. 30 at 1 (https://jobs.perkinelmer.com/job/austin/associate-lab-technologist/20539/15345809) (last accessed June 1, 2020).) The "General Manager, Next Generation Sequencing" job listing states "[i]n this role, the GM, NGS will be responsible for developing and executing on end market

strategies to drive penetration and expand market share for NGS products. This senior leader will lead a team of Product Managers and work with R&D and other key stakeholders to develop and execute on market growth strategies." (Ex. 31 at 1-2 (https://jobs.perkinelmer.com/job/austin/general-manager-next-generation-sequencing/20539/15435120) (last accessed June 1, 2020).) Additionally, PerkinElmer, Inc. previously listed a job opening for an "Associate Scientist" in Austin, Texas, with responsibilities including: "[p]repar[ing] hybridization capture NGS libraries and amplicon panel NGS libraries." (*See* Ex. 32 (https://www.linkedin.com/jobs/view/associate-scientist-at-perkinelmer-inc-1445162139/) (last accessed May 17, 2020).)

18. Defendants have committed acts of direct and indirect infringement in this judicial District, including by making, using, selling, and/or offering for sale, products and/or methods encompassed by the Patents-in-Suit, including the Vanadis® NIPT Assay and the cfDNA Kits.

19. For example, PerkinElmer, Inc. and PerkinElmer Genetics, Inc. offer for sale and sell the Vanadis® NIPT Assay and corresponding system in this District, including through their websites, which are accessible in this District: www.PerkinElmer.com, www.PerkinElmerGenomics.com. On information and belief, customers have used Vanadis® NIPT Assays supplied by PerkinElmer, Inc. and PerkinElmer Genetics, Inc. in this District.

20. For example, PerkinElmer, Inc. and Bioo Scientific Corporation offer for sale and sell the cfDNA Kits in this District, including through their websites, which are accessible in this District: www.PerkinElmer.com, www.PerkinElmer-AppliedGenomics.com, www.chemagen.com, and www.BiooScientific.com. On information and belief, customers have used the cfDNA Kits supplied by PerkinElmer, Inc. and Bioo Scientific Corporation in this District. Additionally, PerkinElmer, Inc. and Bioo Scientific Corporation design, develop,

manufacture, use, and support infringing products, including the NextPrep-Mag™ cfDNA Automated Isolation Kit and NEXTflex® Cell-Free DNA-Seq Kit, in this District, including at facilities at 7050 Burleson Road, Austin, TX 78744. (Ex. 11 (product documentation for NextPrep-Mag™ cfDNA Automated Isolation Kit, listing address "7050 Burleson Road, Austin, Texas 78744"); Ex. 12 (product documentation for NEXTflex® Rapid DNA-Seq Kit 2.0, likewise listing address "7050 Burleson Road, Austin, Texas 78744"); Ex. 13 (providing instruction on "Ordering from PerkinElmer," including a mailing address of "PerkinElmer, 7050 Burleson Rd, Austin, TX 78744, USA"; also providing order form (attached as Ex. 14) with mailing address: "PerkinElmer, 7050 Burleson Rd., Austin, TX 78744").)

21. Venue is also proper because PerkinElmer Genetics, Inc. and Bioo Scientific Corporation are wholly-owned subsidiaries of PerkinElmer, Inc., are completely controlled and dominated by PerkinElmer, Inc., and operate as agents and alter-egos of PerkinElmer, Inc. As the corporate parent, PerkinElmer, Inc. has participated in the commission of patent infringement in this judicial District, including making, using, offing for sale, and/or selling the Vanadis® NIPT Assay and the cfDNA Kits.

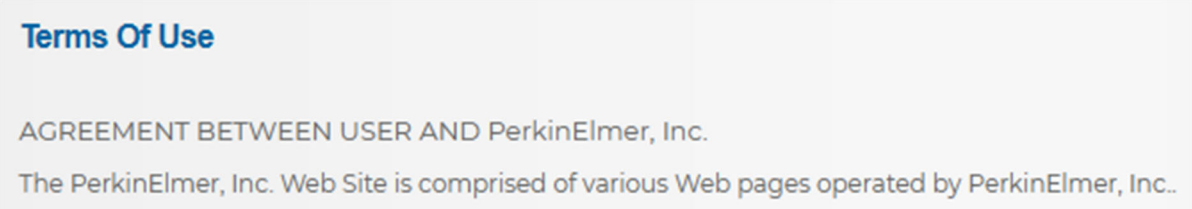
22. Venue is also proper because PerkinElmer, Inc., PerkinElmer Genetics, Inc., and Bioo Scientific Corporation are part of a corporate family that operates as a single company. For example, several of the officers of PerkinElmer, Inc., PerkinElmer Genetics, Inc., and Bioo Scientific Corporation are also officers of other Defendants. According to the most recent Texas Secretary of State filings for the Defendants:

- Prahland R. Singh, President and Chief Executive Officer of PerkinElmer, Inc., is also the President of PerkinElmer Genetics, Inc. and the Vice President of Bioo Scientific Corporation;

- John L. Healy, Vice President and Assistant Secretary of PerkinElmer, Inc., is also the Vice President, Secretary, and Director of PerkinElmer Genetics, Inc., and President, Secretary, Director of Bioo Scientific Corporation;
- David C. Francisco, Treasurer and Director of PerkinElmer, Inc., is also the Treasurer and Director of PerkinElmer Genetics, Inc., and Treasurer and Director of Bioo Scientific Corporation;
- Drew C. Adams previously served as Vice President of PerkinElmer, Inc., Vice President of PerkinElmer Genetics, Inc., and Vice President of Bioo Scientific Corporation;
- Leeanin L. Dennewitz is the Vice President of both PerkinElmer Genetics, Inc. and Bioo Scientific Corporation;
- Kevin A. Oliver is the Vice President of both PerkinElmer Genetics, Inc. and Bioo Scientific Corporation;
- Christopher G. Aborn is the Assistant Treasurer of both PerkinElmer Genetics, Inc. and Bioo Scientific Corporation;
- Jonathan Levin is the Assistant Secretary of both PerkinElmer Genetics, Inc. and Bioo Scientific Corporation; and
- Mary E. Potthoff is the Vice President and Assistant Secretary of PerkinElmer Genetics, Inc. and the Vice President of Bioo Scientific Corporation.

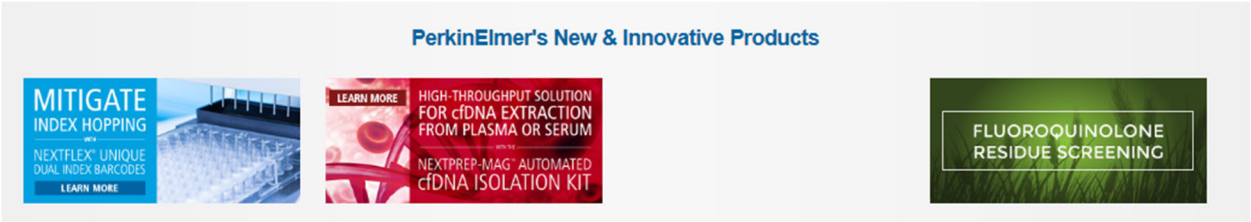
(Exs. 7-10.)

23. Additionally, Defendants' websites demonstrate that they do not maintain corporate separation. For example, Bioo Scientific Corporation's website www.biooscientific.com, which advertises and sells Bioo Scientific Corporations' products, is operated by PerkinElmer, Inc.




(Ex. 33 at 1 (Terms of Use from the Bioo Scientific Corpation's website, located at http://www.biooscientific.com/Terms).) The main webpage for Bioo Scientific Corporation on www.biooscientific.com includes a PerkinElmer logo and a copyright notice for PerkinElmer, Inc. (Ex. 16 at 1, 3.) That webpage lists as an address "7050 Burleson Road, Austin TX, 78744" and the published contact email address is bioo.sales@perkinelmer.com. (Ex. 16 at 1, 3.) The website www.biooscientific.com also includes a "Certificate of Registration of Quality Management System" that was issued to: "PerkinElmer, Inc. 7050 Burleson Rd Austin, TX 78744 USA." (Ex. 27, located at http://www.biooscientific.com/Portals/0/PDF/19-8127-PerkinElmer-Inc-ISO-9001-2015-Certificate-11-14-19.pdf.)

24. PerkinElmer, Inc. also advertises "PerkinElmer's New Innovative Products" on the Bioo Scientific webpage:




(Ex. 16 at 1, 3 (www.biooscientific.com home page).)

25. Bioo Scientific Corporation products, including the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits, are sold on both Bioo Scientific Corporation websites and PerkinElmer, Inc. websites, and Bioo Scientific Corporation's website directs interested parties to order products, including the NextPrep-Mag™ cfDNA Automated Isolation Kit and NEXTflex® Cell-Free DNA-Seq Kits, from "PerkinElmer, 7050

Burleson Rd Austin, TX 78744." (*See* Ex. 21 (Bioo Scientific Corporation website advertising for sale "NextPrep-Mag™ cfDNA Automated Isolation Kit"); Ex. 23 (Bioo Scientific Corporation website advertising for sale "NEXTflex® Cell Free DNA-Seq Kit"); Ex. 13 (providing instruction on "Ordering from PerkinElmer," including a mailing address of "PerkinElmer, 7050 Burleson Rd, Austin, TX 78744, USA"; also providing order form (attached as Ex. 14).) Bioo Scientific Corporation's products, including the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits, are branded with PerkinElmer's logo.


(Ex. 21 (http://shop.biooscientific.com/nextprep-mag-cfdna-automated-isolation-kit/).)

(Ex. 23 (http://shop.biooscientific.com/nextflex-cell-free-dna-seq-kit/).)

26. For example, PerkinElmer Genetics, Inc.'s website https://www.perkinelmergenomics.com, which advertises and sells PerkinElmer Genetics, Inc.'s products, is also operated by PerkinElmer, Inc. The main webpage for PerkinElmer Genetics, Inc. at https://www.perkinelmergenomics.com includes a PerkinElmer logo. (Ex. 15.) In addition, the brochure for PerkinElmer Genetics, Inc.'s Vanadis® NIPT Assay includes a PerkinElmer logo, a copyright notice for PerkinElmer, Inc., and a published contact email address of genomics@perkinelmer.com. (Ex. 34 at 1, 2 (Vanadis® NIPT brochure, available at https://www.perkinelmergenomics.com/Images/Vanadis_NIPT_Sheet_tcm206-222020.pdf).)

27. PerkinElmer Genetics, Inc. products, including the Vanadis® NIPT Assay, are sold on both PerkinElmer Genetics, Inc. and PerkinElmer, Inc. websites.

28. PerkinElmer, Inc. is subject to this Court's jurisdiction pursuant to due process and/or the Texas Long Arm Statute due at least to its substantial business in this State and judicial District, including at least regularly doing and soliciting business at its Austin facilities, and engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in the State of Texas, including in the Western District of Texas. For example, PerkinElmer, Inc. conducts business in the District, by at least making, using, offering for sale and selling products and services that practice the claimed inventions of the Patents-in-Suit, including the Vanadis® NIPT Assay and the cfDNA Kits, including through its websites, which are accessible in this District. In addition, PerkinElmer, Inc. maintains offices and laboratories in this District that make, use, and support the sales of products and services that practice the claimed inventions of the Patents-in-Suit, including at least the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits.

29. This Court has personal jurisdiction over PerkinElmer, Inc. due, *inter alia*, to its continuous presence in, and systematic contact with, this District and its registration in Texas. PerkinElmer, Inc. has established minimum contacts within the forum such that the exercise of jurisdiction over PerkinElmer, Inc. will not offend traditional notions of fair play and substantial justice.

30. Personal jurisdiction exists over PerkinElmer, Inc. because PerkinElmer, Inc. directly and/or through subsidiaries or intermediaries has committed and continues to commit acts of infringement in this District, which led to foreseeable harm and injury to Ravgen.

31. Bioo Scientific Corporation is subject to this Court's jurisdiction pursuant to due process and/or the Texas Long Arm Statute due at least to its substantial business in this State and judicial District, including at least regularly doing and soliciting business at its Austin facilities, and engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in the State of Texas, including in the Western District of Texas. For example, Defendant Bioo Scientific Corporation is a Texas corporation with its principal place of business at 7050 Burleson Road, Austin, TX 78744. For example, Bioo Scientific Corporation conducts business in the District, by at least making, using, offering for sale and selling products and services that practice the claimed inventions of the Patents-in-Suit, including the the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits, including through its websites, which are accessible in this District. In addition, Bioo Scientific Corporation maintains offices and laboratories in this District that make, use, and support the sales of products and services that practice the claimed inventions of the Patents-in-Suit, including at least the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits.

32. This Court has personal jurisdiction over Bioo Scientific Corporation due, *inter alia*, to its continuous presence in, and systematic contact with, this District and its registration in Texas. Bioo Scientific Corporation has established minimum contacts within the forum such that the exercise of jurisdiction over Bioo Scientific Corporation will not offend traditional notions of fair play and substantial justice.

33. Personal jurisdiction exists over Bioo Scientific Corporation because Bioo Scientific Corporation directly and/or through intermediaries has committed and continues to commit acts of infringement in this District, which led to foreseeable harm and injury to Ravgen.

34. PerkinElmer Genetics, Inc. is subject to this Court's jurisdiction pursuant to due process and/or the Texas Long Arm Statute due at least to its substantial business in this State and judicial District, including at least regularly doing and soliciting business, and engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in the State of Texas, including in the Western District of Texas. For example, PerkinElmer Genetics, Inc. conducts business in the District, by at least offering for sale and selling products and services that practice the claimed inventions of the Patents-in-Suit, including the Vanadis® NIPT Assay, including through its websites, which are accessible in this District.

35. This Court has personal jurisdiction over PerkinElmer Genetics, Inc. due, *inter alia*, to its continuous presence in, and systematic contact with, this District and its registration in Texas. PerkinElmer Genetics, Inc. has established minimum contacts within the forum such that the exercise of jurisdiction over PerkinElmer Genetics, Inc. will not offend traditional notions of fair play and substantial justice.

36. Personal jurisdiction exists over PerkinElmer Genetics, Inc. because PerkinElmer Genetics, Inc. directly and/or through subsidiaries or intermediaries has committed and continues to commit acts of infringement in this District, which led to foreseeable harm and injury to Ravgen.

## BACKGROUND OF THE INVENTION

37. Dr. Ravinder S. Dhallan is the founder of Ravgen, Inc. and the inventor of several patents in the field of detection of genetic disorders, including chromosomal abnormalities and mutations. Ravgen's mission is to provide state of the art genetic testing that will enrich the lives of its patients. For example, through the use of its novel techniques in non-invasive prenatal diagnostic testing, Ravgen gives patients the knowledge they need to prepare for their pregnancies and treat diseases at an early stage.

38. Prior to founding Ravgen, Dr. Dhallan was a board-certified emergency room physician, who completed his residency at Mass General (Harvard University School of Medicine). During his time at medical school and his residency, Dr. Dhallan and his wife suffered three miscarriages. At that time, the prenatal diagnostic testing procedures available included (a) non-invasive techniques with low sensitivity and specificity, and (b) tests with higher sensitivity and specificity that were highly invasive and therefore associated with a risk for loss of pregnancy. After discovering the limitations on the available techniques for prenatal testing, Dr. Dhallan made it his mission to invent an improved prenatal diagnostic exam—one that was both non-invasive and accurate. In September of 2000, Dr. Dhallan founded Ravgen (which stands for "Rapid Analysis of Variations in the GENome") to pursue that goal.

39. Prior to Ravgen's inventions, scientists had recognized the need for a genetic testing technique that used "cell-free" or "free" fetal DNA circulating in maternal blood. A technique that

relied on circulating free fetal DNA would require only a simple blood draw from the mother and would therefore be improvement over invasive diagnostic tests.

40. However, at that time, the use of free fetal DNA for detecting chromosomal abnormalities was limited by the low percentage of free fetal DNA that could be recovered from a sample of maternal blood using existing techniques. (*See, e.g.,* Ex. 35 (Lo YM, et al., *Quantitative analysis of fetal DNA in maternal plasma and serum: implications for noninvasive prenatal diagnosis.* AM J HUM GENET. 1998; 62(4):768-775, available at https://doi.org/10.1016/S0140-6736(97)02174-0).) Dr. Dhallan recognized that a method that could increase the percentage of free fetal DNA relative to the free maternal DNA in a sample was necessary to the development of an accurate, non-invasive prenatal diagnostic test.

41. After substantial research, Dr. Dhallan conceived that including an agent that impedes cell lysis (disruption of the cell membrane) if cells are present during sample collection, shipping, handling, and processing would permit the recovery of a larger percentage of cell-free fetal DNA (relative to the cell-free maternal DNA in a sample). Dr. Dhallan hypothesized that this new approach would decrease the amount of maternal cell lysis and therefore lower the amount of cell-free maternal DNA in the sample, thereby increasing the percentage of cell-free fetal DNA. He developed a novel method for processing cell-free fetal DNA that involved the addition of an agent that impedes cell lysis—for example, a membrane stabilizer, a cross-linker, and/or a cell lysis inhibitor—to maternal blood samples. With that novel method, Dr. Dhallan was able to increase the relative percentage of cell-free fetal DNA in the processed sample.

42. Dr. Dhallan understood that his breakthrough laid the foundation for the development of accurate non-invasive prenatal diagnostic tests. For example, he published a paper in the Journal of the American Medical Association (JAMA) in 2004 explaining that "the methods

described herein for increasing the percentage of free fetal DNA provide a solid foundation for the development of a noninvasive prenatal diagnostic test." (Ex. 36 at 8 (Dhallan R., Au W., et al. *Methods to Increase the Percentage of Free Fetal DNA Recovered From the Maternal Circulation.* JAMA. 2004; 291(9):1114–1119, available at https://doi.org/10.1001/jama.291.9.1114).)

43. *JAMA* also ran an editorial alongside Dr. Dhallan's article in 2004, recognizing the significance of his invention to applications in prenatal genetic diagnosis and cancer detection and surveillance:

> In this issue of THE JOURNAL, the findings reported in the study by Dhallan and colleagues on enhancing recovery of cell-free DNA in maternal blood have major clinical implications. Developing a reliable, transportable technology for cell-free DNA analysis impacts 2 crucial areas—prenatal genetic diagnosis and cancer detection and surveillance. In prenatal genetic diagnosis, detecting a fetal abnormality without an invasive procedure (or with fewer invasive procedures) is a major advantage. Likewise in cancer surveillance (e.g., in patients with leukemia), monitoring treatment without having to perform a bone marrow aspiration for karyotype also would be of great benefit
>
> * * *
>
> With prospective studies focusing on clinical applications of these findings, profound clinical implications could emerge for prenatal diagnosis and cancer surveillance.

(Ex. 37 at 1, 3 (Simpson J.L., Bischoff F., *Cell-Free Fetal DNA in Maternal Blood: Evolving Clinical Applications*. JAMA. 2004; 291(9):1135–1137, available at https://doi.org/10.1001/jama.291.9.1135).)

44. In 2007, Dr. Dhallan published a second journal article in The Lancet that presented a study showcasing Ravgen's ability to use its novel technology to detect Down's syndrome using free fetal DNA in a maternal blood sample. (Ex. 38 (Dhallan R., Guo X., et al. *A non-invasive test for prenatal diagnosis based on fetal DNA present in maternal blood: a preliminary study*. LANCET. 2007; 369(9560):474-481, available at https://doi.org/10.1016/S0140-6736(07)60115-

9).) Dr. Dhallan's peers at the *Lancet* also recognized that his innovative test "opens a new era in prenatal screening." (*See* Ex. 39 (Benachi A., Costa J.M., *Non-invasive prenatal diagnosis of fetal aneuploidies.* LANCET. 2007; 369(9560):440–442, available at https://doi.org/10.1016/S0140-6736(07)60116-0).)

45. Dr. Dhallan's publications received worldwide press coverage, from outlets such as CNN, BBC, and Washington Post. (*See* Ex. 40 (L. Palmer, "A better prenatal test?", CNN MONEY, Sept. 12, 2007, available at https://money.cnn.com/2007/09/07/smbusiness/amniocentesis.fsb/index.htm); Ex. 41 ("Hope for safe prenatal gene test" BBC NEWS, Feb 2, 2007, available at http://news.bbc.co.uk/2/hi/health/6320273.stm); Ex. 42 (A. Grander, "Experimental Prenatal Test Helps Spot Birth Defects", WASHINGTON POST, Feb. 2, 2007, available at https://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020200914.html).)

46. The Patents-in-Suit resulted from Dr. Dhallan's years-long research at Ravgen to develop these innovative new methods for detecting genetic disorders.

**PATENTS-IN-SUIT**

47. Ravgen incorporates by reference paragraphs 1–46.

48. The '277 Patent, entitled "Methods For Detection Of Genetic Disorders," was duly and legally issued by the United States Patent and Trademark Office on February 19, 2008. The inventor of the patent is Ravinder S. Dhallan, and the patent is assigned to Ravgen. A copy of the '277 Patent is attached hereto as Exhibit 1.

49. Ravgen is the exclusive owner of all rights, title, and interest in the '277 Patent, and has the right to bring this suit to recover damages for any current or past infringement of the '277 Patent. (*See* Ex. 3.)

50. The '720 Patent, entitled "Methods For Detection Of Genetic Disorders," was duly and legally issued by the United States Patent and Trademark Office on June 1, 2010. The inventor of the patent is Ravinder S. Dhallan, and the patent is assigned to Ravgen. A copy of the '720 Patent is attached hereto as Exhibit 2.

51. Ravgen is the exclusive owner of all rights, title, and interest in the '720 Patent, and has the right to bring this suit to recover damages for any current or past infringement of the '720 Patent. (*See* Ex. 4.)

52. The '277 Patent is directed to, among other things, novel methods used in the detection of genetic disorders. For example, claim 81 of the '277 Patent recites:

> A method for preparing a sample for analysis comprising isolating free fetal nucleic acid from a the sample, wherein said sample comprises an agent that inhibits lysis of cells, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor.

53. The '720 Patent is directed to novel methods for detecting a free nucleic acid in a sample. For example, claim 1 of the '720 Patent recites:

> A method for detecting a free nucleic acid, wherein said method comprises: (a) isolating free nucleic acid from a non-cellular fraction of a sample, wherein said sample comprises an agent that impedes cell lysis, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor; and (b) detecting the presence or absence of the free nucleic acid.

54. The Patents-in-Suit are directed to unconventional, non-routine techniques for preparing and analyzing extracellular circulatory DNA, including for the detection of genetic disorders. The Patents-in-Suit explain that, *inter alia*, the inventions claimed therein overcame problems in the field—for example, that the low percentage of fetal DNA in maternal plasma makes using the DNA for genotyping the fetus difficult—with a novel and innovative solution—

the addition of cell lysis inhibitors, cell membrane stabilizers or cross-linkers to the maternal blood sample, which increase the percentage of cell-free DNA available for detection and analysis:

> The percentage of fetal DNA in maternal plasma is between 0.39-11.9% (Pertl, and Bianchi, *Obstetrics and Gynecology* 98: 483-490 (2001)). **The majority of the DNA in the plasma sample is maternal, which makes using the DNA for genotyping the fetus difficult**. However, methods that increase the percentage of fetal DNA in the maternal plasma allow the sequence of the fetal DNA to be determined, and allow for the detection of genetic disorders including mutations, insertions, deletions, and chromosomal abnormalities. **The addition of cell lysis inhibitors, cell membrane stabilizers or cross-linkers to the maternal blood sample can increase the relative percentage of fetal DNA.** While lysis of both maternal and fetal cells is inhibited, the vast majority of cells are maternal, and thus by reducing the lysis of maternal cells, there is a relative increase in the percentage of free fetal DNA.

(Ex. 1 ('277 Patent) at 32:24–39; Ex. 2 ('720 Patent) at 33:31–46 (emphasis added).)

55. The Patents-in-Suit teach that the benefit of Dr. Dhallan's discovery, an increase in the relative percentage of cell-free DNA, is realized by performance of the claimed method, including through the inclusion of an agent that inhibits the lysis of the cells in a sample:

> An overall increase in fetal DNA was achieved by reducing the maternal cell lysis, and thus, reducing the amount of maternal DNA present in the sample. In this example, formaldehyde was used to prevent lysis of the cells, however any agent that prevents the lysis of cells or increases the structural integrity of the cells can be used. The increase in fetal DNA in the maternal plasma allows the sequence of the fetal DNA to be determined, and provides for the rapid detection of abnormal DNA sequences or chromosomal abnormalities including but not limited to point mutation, reading frame shift, transition, transversion, addition, insertion, deletion, addition-deletion, frame-shift, missense, reverse mutation, and microsatellite alteration, trisomy, monosomy, other aneuploidies, amplification, rearrangement, translocation, transversion, deletion, addition, amplification, fragment, translocation, and rearrangement.

(Ex. 1 ('277 Patent) at 91:44–60; Ex. 2 ('720 Patent) at 92:10–26.)

56. For example, during the prosecution of the '720 Patent at the Patent and Trademark Office, Ravgen explained that the innovative concept of using agents that inhibit cell lysis during

cell-free DNA detection and analysis is recited by the claimed methods of the '720 Patent, including in claim 1:

> Applicant has discovered that the addition of a cell lysis inhibitor to a sample prior to detecting the presence of free nucleic acid can ***significantly and unexpectedly*** increase the proportion of free nucleic acid obtained from the non-cellular fraction of a sample.
>
> * * *
>
> The methods disclosed in claims 1-8, 21-23, and 26 serve a long-felt need in the medical community, and provide unexpected results, and are therefore non-obvious.

(Ex. 5 ('720 File History, June 2, 2009 Response to Office Action) at 12, 14 (emphasis added).)

57. The inventive concept of the Patents-in-Suit of including an agent that inhibits cell lysis—for example, a membrane stabilizer, a cross-linker, and/or a cell lysis inhibitor—with a sample represented a significant improvement in the preparation of samples used for non-invasive testing, including non-invasive prenatal testing to unmask previously undetectable fetal genetic traits. At the time of the invention, it would not have been routine or conventional to add an agent that inhibits cell lysis to a sample to increase the proportion of cell-free nucleic acid of interest obtained from the non-cellular fraction of a sample. In fact, as described above, that inventive concept was recognized by Dr. Dhallan's peers as "an important step in improving detection of cell-free DNA." (Ex. 37 at 3 (Simpson J.L., Bischoff F., *Cell-Free Fetal DNA in Maternal Blood: Evolving Clinical Applications.* JAMA. 2004; 291(9):1135–1137).)

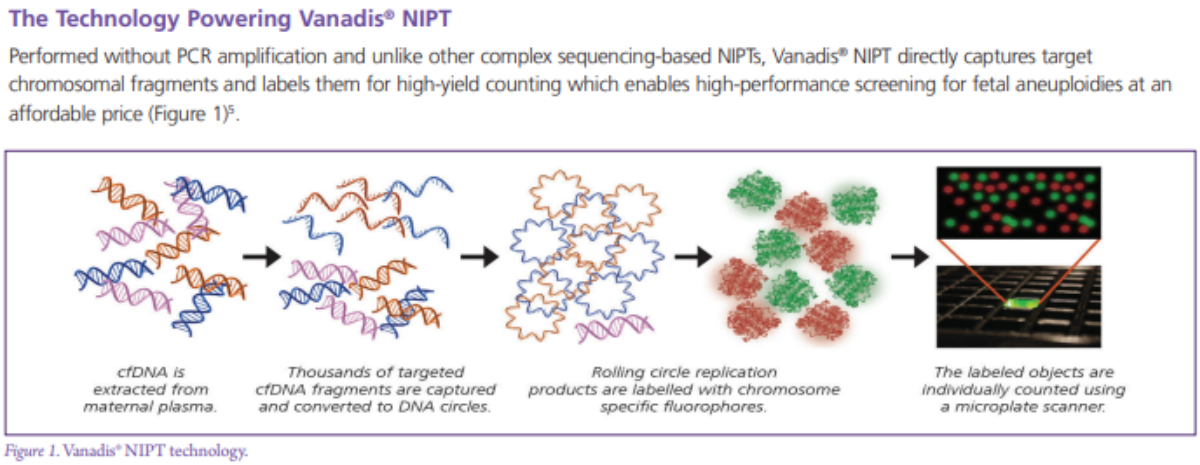
## DEFENDANTS' INFRINGING ACTIVITIES

58. Ravgen incorporates by reference paragraphs 1-57.

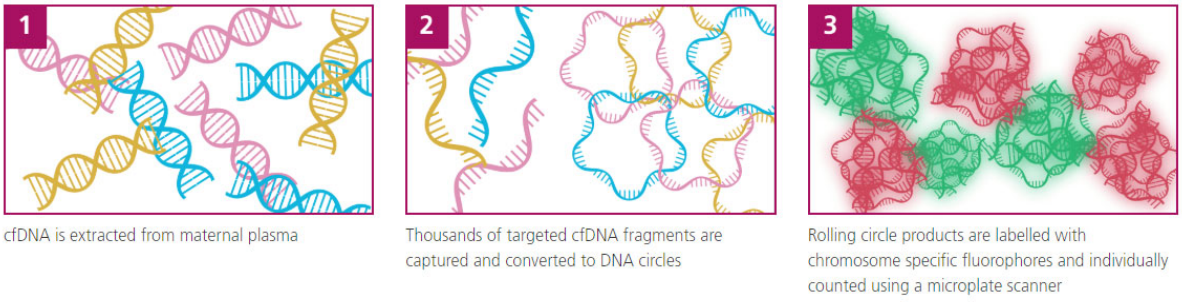
### A. The Vanadis® NIPT Assay

59. On information and belief, PerkinElmer, Inc. and PerkinElmer Genetics, Inc. launched the Vanadis® NIPT Assay in early 2018.

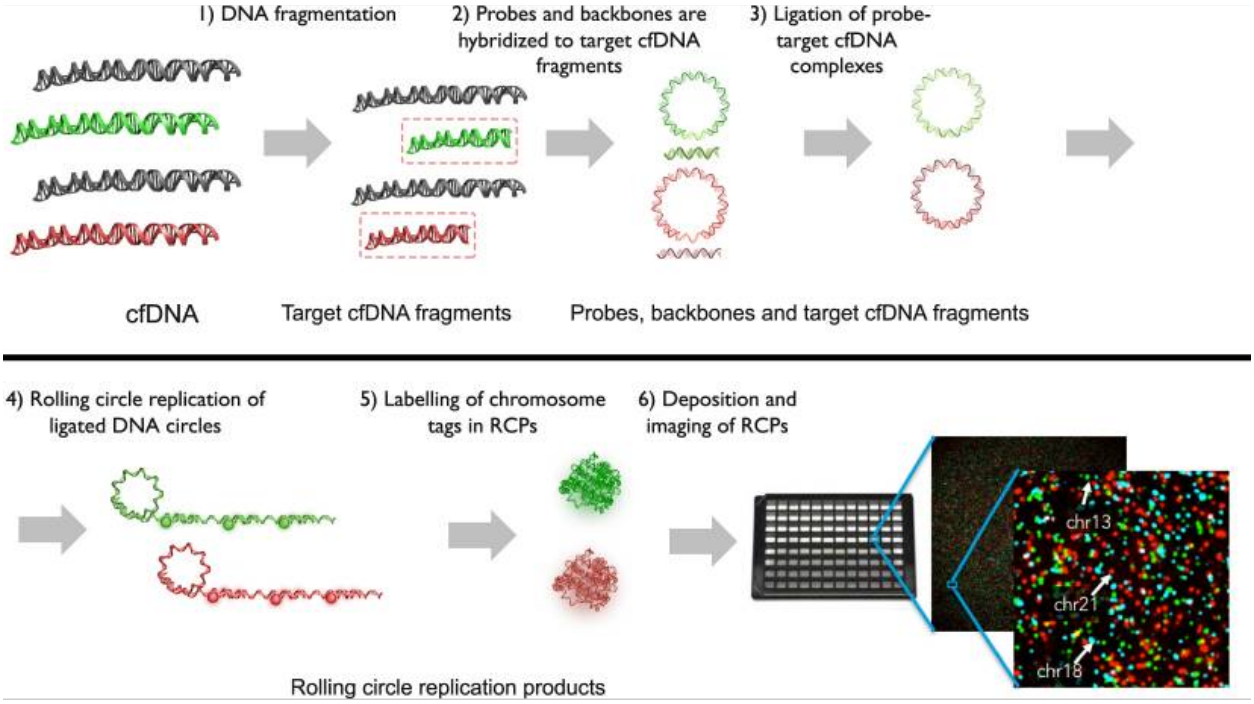
60. The Vanadis® NIPT Assay is a commercial non-invasive prenatal test that extracts, detects, and analyses circulating fetal DNA in maternal blood to determine chromosomal abnormalities in a fetus. (*See* Ex. 43 at 1 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT.* SCI REP. 2018; 8(1):4549, available at https://doi.org/10.1038/s41598-018-22606-0) (describing "a novel cost effective method, the Vanadis® NIPT assay, designed for high precision digitally-enabled measurement of chromosomal aneuploidies in maternal plasma").) An overview of that process is depicted below:




(Ex. 34 at 1 (Vanadis® NIPT brochure copyrighted by PerkinElmer, Inc.).)




(Ex. 44 at 3 (Marketing materials for Vanadis® NIPT, available at https://prenataltesting.perkinelmer.com/screening_expertise/non-invasive_prenatal_testing).)




(Ex. 43 at 2 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT*. SCI REP. 2018; 8(1):4549) (Figure 1: "Vanadis NIPT assay. (1) Extracted cfDNA is first subjected to specific fragmentation using a restriction enzyme. The resulting target cfDNA fragments are similar in size and GC content and are derived from the chromosomes of interest. (2) Probes, designed to hybridize to the target cfDNA fragments to form circular DNA complexes, are mixed with the target cfDNA fragments, backbone oligos and DNA ligase. (3) By allowing the target cfDNA fragments to hybridize to the probe complex and DNA ligase to seal the nicks, covalently closed circles are generated that each includes a cfDNA target fragment and a corresponding chromosomal tag. All DNA that is not circularized is removed with exonucleases. (4) The DNA circles are copied about 1000 times by rolling-circle-amplification (RCA) to generate one rolling circle replication product (RCP), a single stranded concatemer amplification product. (5) The RCPs self-assemble to submicron-sized DNA objects. Because each RCP includes copies of a chromosomal tag it can be recognized by a corresponding fluorescently labeled

oligonucleotide. (6) The labelled RCPs are then deposited to a 96-well nanofilter microplate. The microplate has a nanofilter membrane in the bottom to allow the RCPs to be captured on the plate bottom, while buffer and non-hybridized fluorophores are washed through the membrane. The deposited RCPs are finally imaged through the nanofilter using the Vanadis View imaging instrument.").)

61. The Vanadis® NIPT System for processing the Vanadis® NIPT Assay "consists of three instruments: Vanadis Extract® for cfDNA extraction, Vanadis Core® for cfDNA analysis, and the molecule counting unit, Vanadis View®. All three instruments are controlled through the system software which guides the workflow and monitors the assay performance by conducting the built-in Vanadis® NIPT quality assessment procedures. After quality assessment, the results are sent to the software for trisomy risk calculation and reporting, *e.g.* LifeCycle™ for Prenatal Screening." (Ex. 45 at 1 (a white paper entitled "Vanadis® NIPT System: High-Precision Prenatal Aneuploidy Screening with Automated Quality Assessment," available at https://www.perkinelmer.com/lab-solutions/resources/docs/WP_VanadisNIPT_Quality-Assessment_1599-9868.pdf, copyrighted by PerkinElmer, Inc.).)

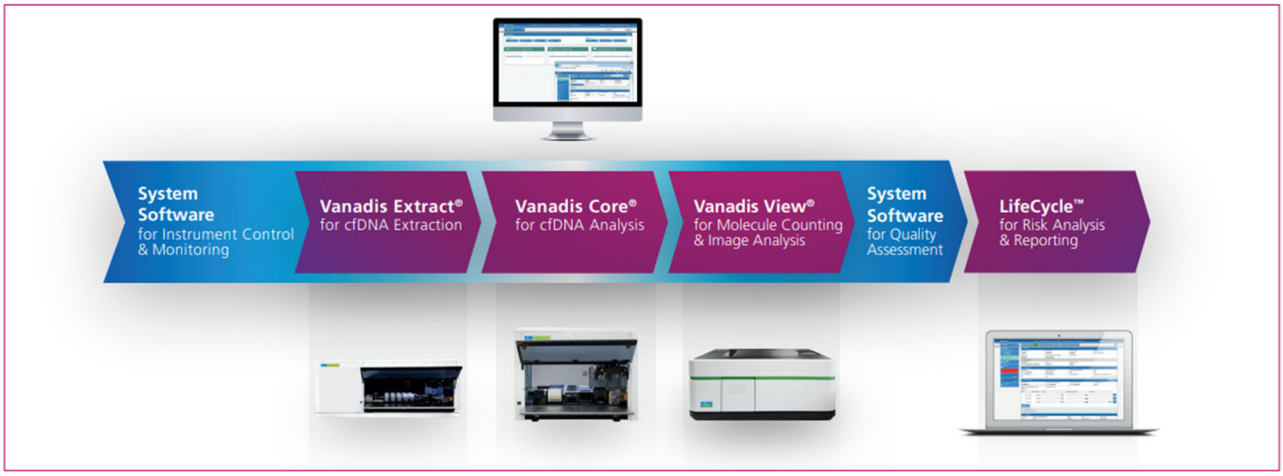


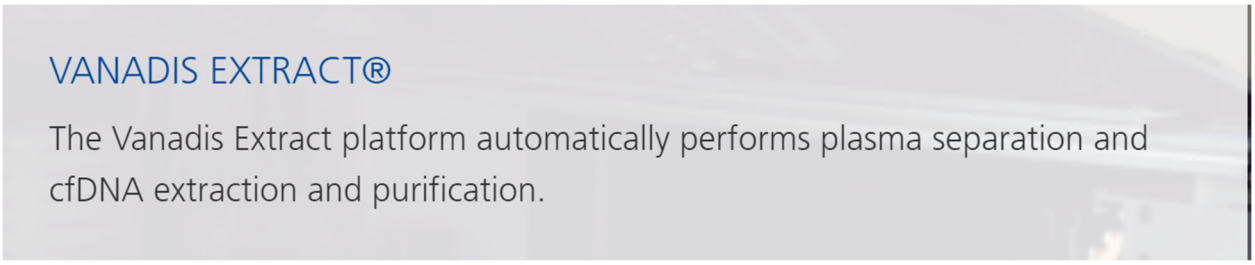

*Figure 1.* The automated workflow of the Vanadis NIPT system. After image analysis in Vanadis View the multi-dimensional quality assessment is performed by the system software.

(Ex. 45 at 2.)

62. The Vanadis® NIPT Assay uses samples containing an agent that inhibits cell lysis. For example, the Vanadis® NIPT Assay uses maternal blood samples that are collected in Streck tubes. (*See* Ex. 43 at 5 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT.* SCI REP. 2018; 8(1):4549) ("An average of 9.5 mL whole blood was collected in Cell-free DNA BCT® blood collection tubes (Streck)"); Ex. 46 at 2 (a white paper entitled "Vanadis® NIPT system: Proof of principle data for trisomy screening," available at https://prenataltesting.perkinelmer.com/files/196/WP_VanadisNIPT_Clinical_1599-9814-06.pdf, and copyrighted by PerkinElmer, Inc.) ("To demonstrate the Vanadis technical approach 441 de-identified blinded samples were analyzed. . . . Samples were collected in STRECK® tubes from pregnant women during gestational weeks 10–18.").)

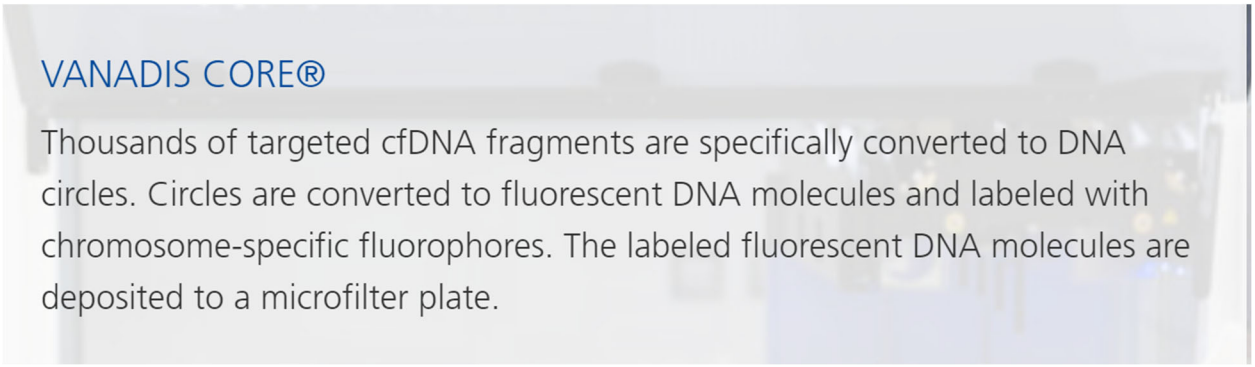
63. The Streck Cell-Free DNA Blood Collection Tube ("BCT") includes an agent that inhibits cell lysis. A Streck Cell-Free DNA BCT® "stabilizes nucleated blood cells. The unique preservative ***limits the release of genomic DNA, allowing isolation of high-quality cell-free DNA***. Cell-Free DNA BCT® has also been demonstrated to minimize the degradation of circulating tumor cells (CTCs). By ***limiting cell lysis***, the specialized chemistry provides sample integrity during storage, shipping and handling of blood samples. Cell-free DNA and gDNA are stable for up to 14 days at 6 °C to 37 °C. CTCs are stable for up to 7 days at 15 °C to 30 °C." (Ex. 47 at 2 (product documentation for the Streck Cell-Free DNA BCT® blood collection tube, available at https://www.streck.com/products/stabilization/cell-free-dna-bct/#resources) (emphasis added).)

64. The Vanadis Extract® instrument extracts the cell-free fetal DNA from the sample of maternal blood collected in a Streck Cell-Free DNA BCT®:




(Ex. 17 at 2 (the "Vanadis Extract®" tab of the Vanadis® NIPT System marketing materials available at https://prenataltesting.perkinelmer.com/products/vanadis_nipt_system); *see also, e.g.,* Ex. 46 at 2 (a white paper entitled "Vanadis® NIPT system: Proof of principle data for trisomy screening," and copyrighted by PerkinElmer, Inc.) ("DNA was extracted using an optimized, single-step bead-based DNA extraction protocol."); Ex. 43 at 5 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT.* SCI REP. 2018; 8(1):4549) ("Plasma was isolated within five days from blood draw. An average of 9.5 mL whole blood was collected in Cell-free DNA BCT® blood collection tubes (Streck) via a double centrifugation protocol consisting of a first centrifugation step at 1342 × g for 30 minutes, transfer of the plasma fraction to a secondary tube and a second centrifugation step at 2267 × g for 20 minutes. . . **cfDNA was extracted from 3 ml of plasma via a bead based protocol**.") (emphasis added).)

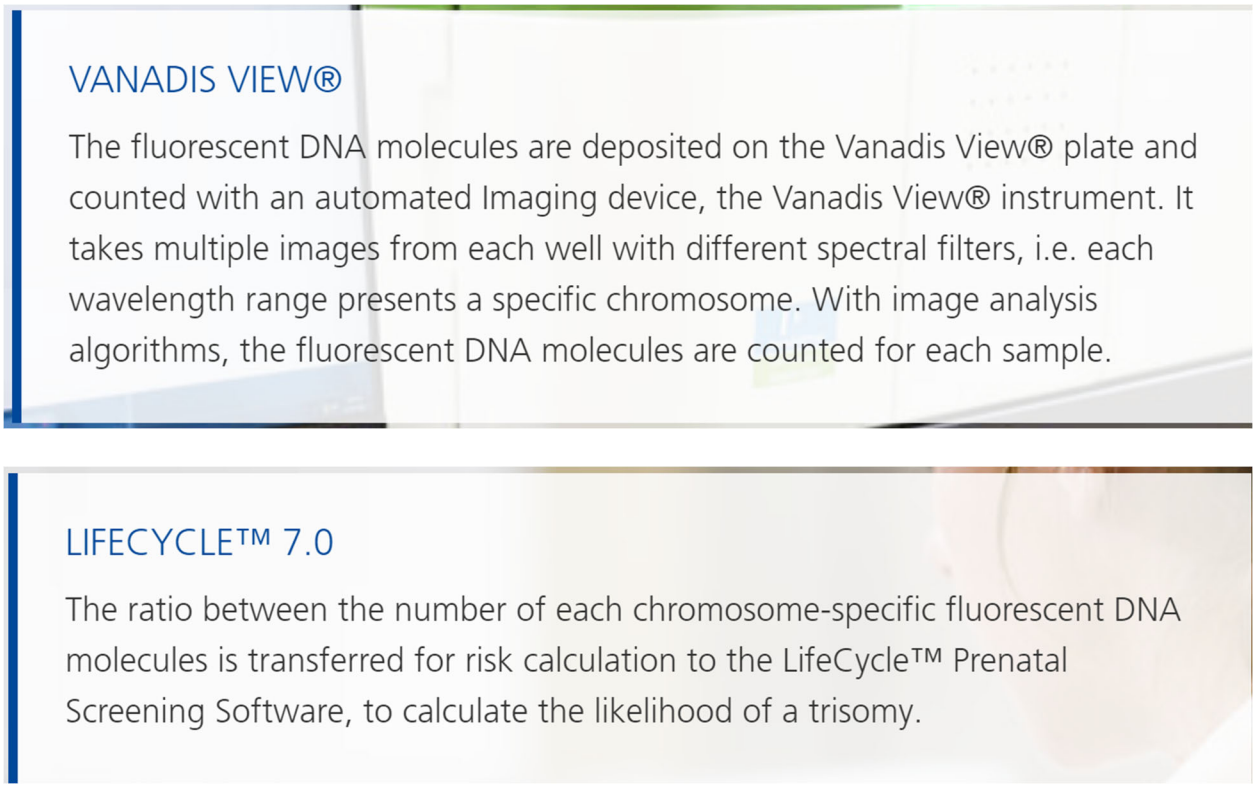
65. The Vanadis Core® instrument prepares the extracted cell-free DNA for analysis by incorporating target DNA fragments into DNA circles using probes specific to particular loci on chromosomes of interest and labeling (or "tagging") them with fluorophores:



(Ex. 17 at 5 (the "Vanadis Core®" tab of the Vanadis® NIPT System marketing materials available at https://prenataltesting.perkinelmer.com/products/vanadis_nipt_system); *see also*, *e.g.,* Ex. 46 at 2 (a white paper entitled "Vanadis® NIPT system: Proof of principle data for trisomy screening," and copyrighted by PerkinElmer, Inc.) ("DNA was extracted using an optimized, single-step bead-based DNA extraction protocol. DNA was then subjected to the Vanadis technology to convert target DNA fragments from chromosome 21, 18, 13 and a reference chromosome into objects labeled with different fluorophores for downstream counting."); Ex. 43 at 5, 6 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT.* SCI REP. 2018; 8(1):4549):

> The Vanadis NIPT assay relies on incorporating target cfDNA fragments into DNA circles. Circularization of cfDNA target fragments generated by MseI digestion of the cfDNA was enabled by addition of the Vanadis NIPT probe set consisting of approximately 12 000 **locus specific probe oligonucleotides** which each contains a middle region complementary to a selected MseI digested target cfDNA fragment. **Target cfDNA fragments were selected to be unique to the chromosomes of interest**, to have uniform length and melting temperature and to not contain any known polymorphic bases. (at 6.)
>
> * * *
>
> Following restriction endonuclease digestion, a 70 µl hybridization and ligation reaction was added to **produce a reaction mixture containing 5 pM per locus-specific probe**, 508 nM per backbone (IDT), 80 U of Taq DNA Ligase (Qiagen), 1 mM NAD+ (New England Biolabs), 100 mM NaCl, 15 mM $MgCl_2$, 10 mM Tris-HCl pH 8 and 0.11% w/v Tween20. (at 5.)
>
> * * *
>
> Following RCA a 12 µl labeling master mix was added to each reaction consisting of 60 nM of each **fluorescent labeling oligonucleotide complementary to a chromosomal tag in the backbone,** 12 × SSC buffer and 0.6% Tween20. (at 6.)

66. The Vanadis View® and LifeCycle™ 7.0 software counts and analyzes the tagged cfDNA fragments:




(Ex. 17 at 9, 12 (the "Vanadis View®" and "LifeCycle™ 7.0" tabs of the Vanadis® NIPT System marketing materials available at https://prenataltesting.perkinelmer.com/products/vanadis_nipt_system); *see also*, *e.g.,* Ex. 46 at 2 (a white paper entitled "Vanadis® NIPT system: Proof of principle data for trisomy screening," and copyrighted by PerkinElmer, Inc.) ("Each microplate well corresponded to one patient sample, and for all samples an average of 450,000 counts were generated for each chromosome. Samples were classified by comparing each sample to the average counted ratio. Samples three standard deviations from the mean were classified as positive."); Ex. 43 at 6 (Dahl, F., Ericsson, O., Karlberg, O. et al. *Imaging single DNA molecules for high precision NIPT.* SCI REP. 2018;

8(1):4549) ("The plates were imaged and analyzed using a Vanadis View™ microplate scanner (PerkinElmer)").)

67. PerkinElmer, Inc. and PerkinElmer Genetics, Inc. make the Vanadis® NIPT Assay and associated system, offer them for sale, and sell them to customers throughout the Unites States. For example, PerkinElmer Genetics, Inc. advertises the system on its website: "Vanadis® NIPT is a high-precision non-invasive prenatal assay designed to accurately screen for the three most common chromosomal anueploidy syndromes (Trisomy 21, 18, and 13)." (Ex. 18 at 1 (https://www.perkinelmergenomics.com/healthcare-providers/Vanadis-NIPT/index.html).) PerkinElmer, Inc. also advertises the system on its website: "Noninvasive prenatal testing (NIPT) consists in analyzing cell-free DNA (cfDNA) circulating in the maternal blood in order to detect Down's syndrome and other fetal chromosomal abnormalities." (Ex. 44 at 1 (Marketing materials for Vanadis® NIPT).) On information and belief, PerkinElmer, Inc. and PerkinElmer Genetics, Inc. instruct users to perform the Vanadis® NIPT Assay using associated system as described above, for example, by providing marketing materials, product manuals, and other instructions for use. (https://prenataltesting.perkinelmer.com/products/vanadis_nipt_system (Video showing "Automated Workflow From Primary Tube To Final Result"); Ex. 45 (White Paper entitled "Vanadis® NIPT System: High-Precision Prenatal Aneuploidy Screening with Automated Quality Assessment"); Ex. 34 (Product documentation for Vanadis® NIPT, available at https://www.perkinelmergenomics.com/Images/Vanadis_NIPT_Sheet_tcm206-222020.pdf); Ex. 44 (Marketing materials for Vanadis® NIPT, available at https://prenataltesting.perkinelmer.com/screening_expertise/non-invasive_prenatal_testing).)

68. PerkinElmer, Inc. and PerkinElmer Genetics, Inc. use the Vanadis® NIPT Assay as described above to process samples at their laboratory facilities. (*See* Ex. 25 at 1 ("PerkinElmer,

Inc., (NYSE: PKI), a global leader committed to innovating for a healthier world, today announced that PerkinElmer Genomics will begin processing samples with the Vanadis® fully automated non-invasive prenatal testing (NIPT) system at its state-of-the-art CLIA and CAP-certified clinical laboratory in Pittsburgh, Pennsylvania and its PerkinElmer Lab Services affiliate laboratory in Kuala Lumpur, Malaysia. In addition to offering full service NIPT testing, these two laboratories will also serve as overflow and demonstration sites for global systems customers."); Ex. 48 at 1 (news release entitled "PerkinElmer Launches Clinical Whole Genome Sequencing Services," available at https://www.perkinelmergenomics.com/blog/2017/08/03/perkinelmer-launches-clinical-whole-genome-sequencing-services/) ("PerkinElmer Genetics has two state-of-the-art CLIA-certified clinical laboratories based in Pittsburgh, PA and Branford, CT that process more than 500,000 samples a year. Their testing menus include newborn screening, biochemical profiling, 2nd tier molecular confirmatory testing, Sanger and NGS-based panels, and exome and genome sequencing."); Ex. 49 ("Lab Accreditation" page, at https://www.perkinelmergenomics.com/about-us/lab-accreditation/index.html, linking to "PerkinElmer Genomics" laboratories accreditations which are registered under "PerkinElmer Genetics, Inc."); *cf.* Ex. 50 (https://www.perkinelmergenomics.com/Images/CLIA2020-22_tcm206-214033.pdf); Ex. 26 ("Prenatal and Reproductive Test Requisition Form," available at https://www.perkinelmergenomics.com/Images/Prenatal_Reproductive_TRF_tcm206-222160.pdf).)

**B. The cfDNA Kits**

69. PerkinElmer, Inc. and Bioo Scientific Corporation make, use, and commercialize kits for genetic testing using cell-free DNA, including the chemagic™ cfDNA 5k Kits, the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits.

70. For example, the chemagic™ cfDNA 5k Kits and the NextPrep-Mag™ cfDNA Automated Isolation Kits are designed to extract cell-free DNA, including circulating fetal free DNA or circulating tumor DNA, from a sample. (Ex. 51 ("Bioo Scientific News" post entitled "Bioo Scientific Launches Kit Offering Robust, Automation-friendly cfDNA Isolation," available at http://www.biooscientific.com/Company/Whats-New/Bioo-Scientific-Launches-cfDNA-Isolation-Kit) ("cfDNA isolated using this kit can be used for applications including circulating fetal DNA studies and cancer diagnostic related liquid biopsy studies using methods such as PCR and next generation sequencing. . . . the discovery of circulating fetal DNA in the maternal circulation and the development of advanced sequencing technologies are facilitating noninvasive prenatal testing, NIPT."); Ex. 24 (product documentation for the chemagic™ cfDNA 5k Kit H24) ("Automated isolation of cell-free tumor or fetal DNA from 3 - 5 ml plasma").) The NextPrep-Mag™ cfDNA Automated Isolation Kits are designed to be used on PerkinElmer, Inc.'s chemagic™ 360 and chemagic™ Prepito® instruments. (Ex. 52 at 1 (product documentation for the "NextPrep-Mag™ cfDNA Automated Isolation Kit," available at https://perkinelmer-appliedgenomics.com/home/products/cfdna-cfrna-isolation/nextprep-mag-cfdna-automated-isolation-kit/#content).) The chemagic™ cfDNA 5k Kits are designed to be used on PerkinElmer, Inc.'s chemagic™ 360 instruments. (Ex. 24 (product documentation for the chemagic™ cfDNA 5k Kit H24).)

71. The NEXTflex® Cell-Free DNA-Seq Kits are designed to prepare multiplexed libraries from the extracted cell free DNA in order to optimize analysis of that DNA. (Ex. 51.) The NEXTflex® rapid DNA-seq Kits are designed to be compatible with the PerkinElmer Sciclone® G3 NGS and NGSx workstations. (Ex. 19 at 1.)

72. In February 2015, Bioo Scientific Corporation launched the NextPrep-Mag™ cfDNA Automated Isolation Kits and NEXTflex® Cell-Free DNA-Seq Kits. (*See* Ex. 51 ("Bioo Scientific News" post entitled "Bioo Scientific Launches Kit Offering Robust, Automation-friendly cfDNA Isolation," available at http://www.biooscientific.com/Company/Whats-New/Bioo-Scientific-Launches-cfDNA-Isolation-Kit) (published Feb. 2, 2015, accessed May 17, 2020).) On information and belief, PerkinElmer, Inc. acquired the NextPrep-Mag™ cfDNA Automated Isolation Kits and NEXTflex® Cell-Free DNA-Seq Kits through its purchase of Bioo Scientific Corporation in 2016.

73. The NextPrep-Mag™ cfDNA Automated Isolation Kits and the NEXTflex® Cell Free DNA-Seq Kits are currently made, offered for sale, and sold by both Bioo Scientific Corporation and PerkinElmer, Inc. (*See* Ex. 21 (advertising for sale the NextPrep-Mag™ cfDNA Automated Isolation Kit); Ex. 20 (same); Ex. 23 (advertising for sale the NEXTflex® Cell-Free DNA-Seq Kit); Ex. 53 (https://perkinelmer-appliedgenomics.com/home/products/library-preparation-kits/dna-library-prep-kits/nextflex-cell-free-dna-seq-kit/) (same).)

74. On information and belief, PerkinElmer, Inc. has been making, using, and commercializing the chemagic™ cfDNA 5k Kits since at least 2016. (Ex. 54 (marketing materials for chemagic™ cfDNA/cfNA 5k Kits, including product numbers, copyrighted by PerkinElmer, Inc., and listing copyright date as 2016) (available at https://www.perkinelmer.com/lab-solutions/resources/docs/TCH_Automated-Cell-Free-DNA-Isolation-from-2-5-ml-of-Plasma-Samples_CT16-8-16-1607.pdf).) PerkinElmer, Inc. currently makes, uses, and commercializes the chemagic™ cfDNA 5k Kits. (Ex. 24 (product documentation for the chemagic™ cfDNA 5k Kit H24, bearing the "PerkinElmer" logo).)

75. The cfDNA Kits are used to extract and process cell-free DNA for detection. For example, the flowchart below provides an overview of the "methodology developed at Bioo Scientific, a PerkinElmer® Company, for both rapid high-throughput automated extraction of cfDNA from high volumes of plasma (5 mL) and for preparation of whole-genome cfDNA libraries from the extracted cfDNA, in a fully automated fashion."

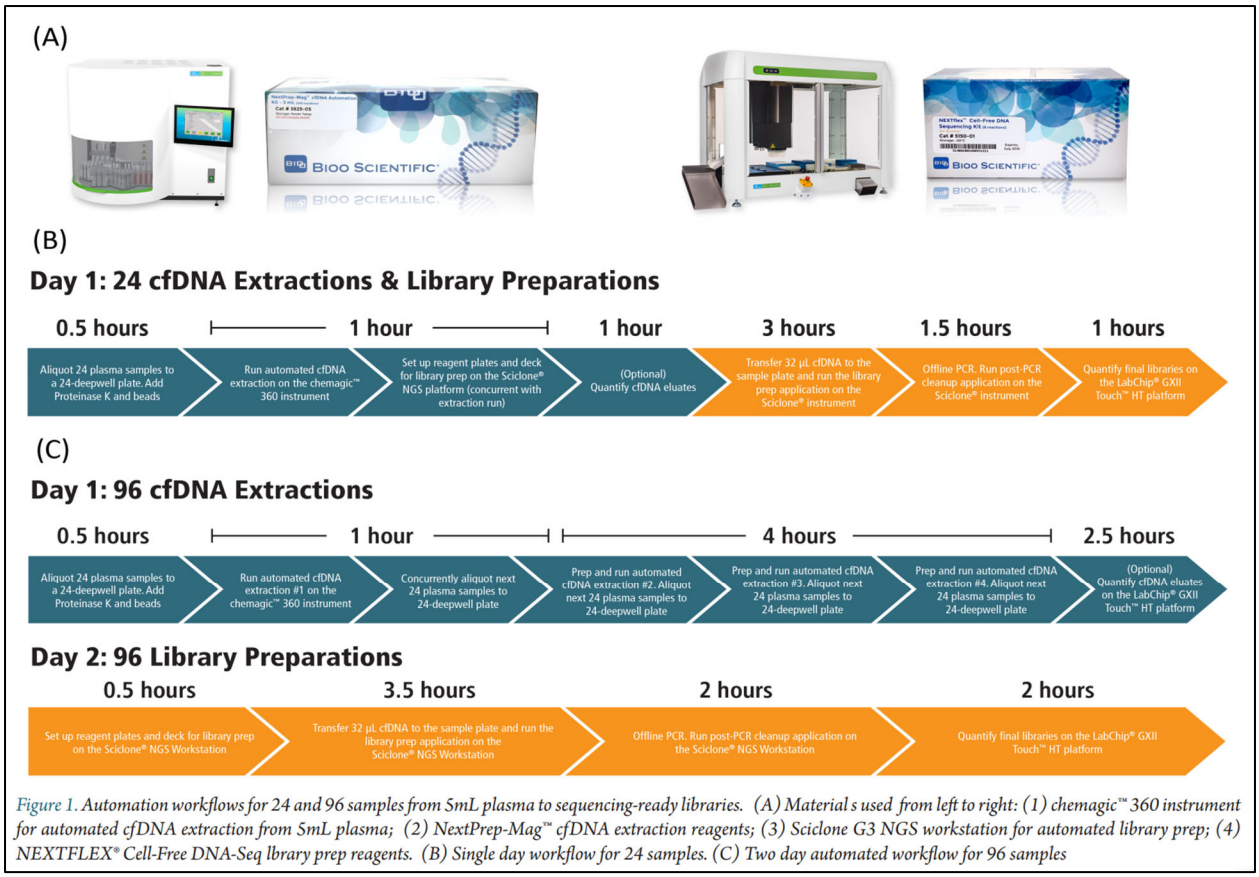



*Figure 1. Automation workflows for 24 and 96 samples from 5mL plasma to sequencing-ready libraries. (A) Material s used from left to right: (1) chemagic™ 360 instrument for automated cfDNA extraction from 5mL plasma; (2) NextPrep-Mag™ cfDNA extraction reagents; (3) Sciclone G3 NGS workstation for automated library prep; (4) NEXTFLEX® Cell-Free DNA-Seq lbrary prep reagents. (B) Single day workflow for 24 samples. (C) Two day automated workflow for 96 samples*

(Ex. 55 (a poster-format presentation authored by M. Carter (contact information of Matthew.Carter@PerkinElmer.com) et al., entitled "An Automated Workflow that Enables Cell-Free DNA Extraction & Whole-Genome NGS Library Preparation from 24 Plasma Samples in a Single Workday," and available at https://chemagen.com/wp-content/uploads/2018/10/SLAS_Poster_cfDNA_automated_FINAL.pdf).)

76. The chemagic™ cfDNA 5k Kits and the NextPrep-Mag™ cfDNA Automated Isolation Kits extract cell-free DNA, for example circulating fetal free DNA and circulating tumor DNA, from a sample. (Ex. 51 ("Bioo Scientific News" post entitled "Bioo Scientific Launches Kit Offering Robust, Automation-friendly cfDNA Isolation," available at http://www.biooscientific.com/Company/Whats-New/Bioo-Scientific-Launches-cfDNA-Isolation-Kit) ("The cfDNA isolated using this kit can be used for applications including circulating fetal DNA studies . . . Additionally, the discovery of circulating fetal DNA in the maternal circulation and the development of advanced sequencing technologies are facilitating noninvasive prenatal testing, NIPT."); Ex. 52 (product documentation for the "NextPrep-Mag™ cfDNA Automated Isolation Kit"); Ex. 24 (product documentation for the chemagic™ cfDNA 5k Kit H24).)

77. The chemagic™ cfDNA 5k Kits and the NextPrep-Mag™ cfDNA Automated Isolation Kits use samples containing an agent that inhibits cell lysis. For example, the chemagic™ cfDNA 5k Kits and the NextPrep-Mag™ cfDNA Automated Isolation Kits process blood samples collected in Streck Cell-Free DNA BCT® tubes. (*See* Ex. 11 at 4 (product documentation for "NextPrep-Mag™ cfDNA Automated Isolation Kit") ("The NextPrep-Mag™ cfDNA Automated Isolation Kit is designed for extraction of cell-free DNA (cfDNA) from up to 5 mL of human plasma" from "blood collected in . . . Streck BCT® tubes"); Ex. 55 (a poster-format presentation entitled "An Automated Workflow that Enables Cell-Free DNA Extraction & Whole-Genome NGS Library Preparation from 24 Plasma Samples in a Single Workday") ("[P]lasma from the first-trimester pregnant donor was obtained from blood collected in Streck BCT® tubes and fractionated, using a double-spin protocol."); Ex. 56 at 3 (product manual for the chemagic™ cfDNA 5k Kit H24, available at https://chemagen.com/wp-content/uploads/2019/10/art-1304-

chemagic-cfDNA-5k-Kit-H24-VD190617-Detailed-Manual.pdf) ("The kit is designed for the use with human plasma samples derived from EDTA, citrate or Streck Cellfree DNA BCT® tubes."); Ex. 24 at 1 (product documentation for the chemagic™ cfDNA 5k Kit H24) (same).)

78. As described above, samples collected in Streck Cell-Free DNA BCT® tubes, including blood samples, contain an agent that inhibits cell lysis. (*See* Ex. 47 at 2 (product documentation for the Streck Cell-Free DNA BCT® blood collection tube).)

79. The NEXTflex® Cell-Free DNA-Seq Kit produces DNA libraries from the extracted cell free DNA for sequencing. (Ex. 53 at 2 ("The NEXTflex® Cell Free DNA-Seq Kit 2.0 can produce libraries from 10 ng of cell free DNA for circulating tumor DNA (ctDNA) or cell free fetal DNA (cffDNA) analysis, in two hours. This low-input library preparation kit delivers high coverage quality and reduced bias for Illumina® sequencing applications."); Ex. 55 (a poster-format presentation entitled "An Automated Workflow that Enables Cell-Free DNA Extraction & Whole-Genome NGS Library Preparation from 24 Plasma Samples in a Single Workday") ("Library preparation for whole genome sequencing. An equal volume (32 µl) of each extracted cf DNA was transferred to a 96 well hard-shelled PCR plate and used as input for whole genome library preparation on the Sciclone® G3 NGS workstation. Libraries were made using the NEXTflex® Cell-Free DNA-seq kit for Illumina® platforms, with barcoded adapters (Bioo Scientific®) diluted 1:8. Libraries were analyzed for yield and size distribution on the LabChip® GX Touch™ HT platform (PerkinElmer®). Libraries from the pregnant donors were sequenced on the Illumina®").)

80. The product manual for NEXTflex® Cell-Free DNA-Seq Kits instructs users to "[e]xamine library by electrophoresis to ensure proper library sizing and to verify exclusion of contaminating small and large fragments (recommended: LabChip® GXII Touch™ HT instrument

(PerkinElmer®)." (Ex. 57 at 15 (NEXTflex® Cell-Free DNA-Seq kit manual, available at https://c2x9r4v3.stackpathcdn.com/wp-content/uploads/marketing/NEXTFLEX/cell_free_dna-seq/NOVA-5150-01_NEXTFLEX_Cell_Free_DNA-Seq_Kit_19.02-002.pdf)); *cf.* Ex. 55 (a poster-format presentation entitled "An Automated Workflow that Enables Cell-Free DNA Extraction & Whole-Genome NGS Library Preparation from 24 Plasma Samples in a Single Workday") ("Libraries were analyzed for yield and size distribution on the LabChip® GX Touch™ HT platform (PerkinElmer®).").)

81. PerkinElmer, Inc. and Bioo Scientific Corporation instruct users to use the chemagic™ cfDNA 5k Kits, the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits as described above, for example, by providing product manuals for those kits. (*See, e.g.,* Ex. 56 (product manual for the chemagic™ cfDNA 5k Kit H24, available at https://chemagen.com/wp-content/uploads/2019/10/art-1304-chemagic-cfDNA-5k-Kit-H24-VD190617-Detailed-Manual.pdf); Ex. 58 (NextPrep-Mag™ cfDNA Isolation Kit (For <1mL-3mL Plasma Samples) manual, available at https://c2x9r4v3.stackpathcdn.com/wp-content/uploads/marketing/NextPrep/3825-01-NextPrep-Mag-cfDNA-Isolation-Kit-1-mL-3-mL-16-50-isolations_v18.12.pdf); Ex. 59 (NextPrep-Mag™ cfDNA Isolation Kit (For 3mL-5mL Plasma Samples) manual, available at https://c2x9r4v3.stackpathcdn.com/wp-content/uploads/marketing/NextPrep/3825-03-NextPrep-Mag-cfDNA-Isolation-Kit-3-mL-5-mL-50-isolations_v18.12.pdf); Ex. 57 (NEXTflex® Cell Free DNA-Seq Kit 2.0 manual).)

82. PerkinElmer, Inc. and Bioo Scientific Corporation promote the use of the NextPrep-Mag™ cfDNA Automated Isolation Kits with the NEXTflex® Cell-Free DNA-Seq Kits for the extraction of cell-free DNA from plasma and the library preparation of the extracted cell-free DNA for sequencing. (*See, e.g.,* Ex. 52 (product documentation for the "NextPrep-Mag™

cfDNA Automated Isolation Kit") ("The cfDNA isolated with the NextPrep-Mag™ cfDNA kits have been verified to be compatible with manual and automated NGS library construction on the Sciclone® G3 NGSx workstation and the Zephyr® NGS workstation using the NEXTflex® Cell-Free DNA-Seq kit 2.0 for Illumina® sequencing."); Ex. 20 (same); Ex. 53 at 2 ("We recommend using the NextPrep-Mag™ cfDNA Automated Isolation Kit for isolation of circulating cfDNA from blood plasma prior to library prep with the NEXTflex® Cell Free DNA-Seq Kit 2.0."); Ex. 55 (a poster-format presentation entitled "An Automated Workflow that Enables Cell-Free DNA Extraction & Whole-Genome NGS Library Preparation from 24 Plasma Samples in a Single Workday") ("This poster describes methodology developed at Bioo Scientific, a PerkinElmer® Company, for both rapid high-throughput automated extraction of cfDNA from high volumes of plasma (5 mL) and for preparation of whole-genome cfDNA libraries from the extracted cfDNA, in a fully automated fashion.").)

## C. Defendants' Knowledge Of The Ravgen Patents

83. On information and belief, Defendants have been aware of the Patents-in-Suit and the fact that performance of the Defendants' cell-free DNA tests, including use of the Vanadis® NIPT Assay and the cfDNA Kits, practice the claimed inventions of those patents since at least May 2020. For example, on May 15, 2020, Ravgen, through outside counsel, sent a letter to Defendants, identifying the '720 and '277 Patents and informing them that "PerkinElmer has used and continues to use its patented technology by making, using, selling, offering to sell, and/or importing that include the patented methods, such as for example, PerkinElmer's Vanadis System[] and its NextPrep-Mag cfDNA Automated Isolation Kit." (*See* Ex. 6.) Although that letter requested a meeting to discuss a potential license, Defendants failed to respond. (*Id.*)

84. Despite their knowledge of the Patents-in-Suit and of their infringement of those patents, Defendants have continued to willfully infringe the Patents-in-Suit so as to obtain the significant benefits of Ravgen's innovations without paying compensation to Ravgen. For example, Defendants have continued to use the claimed methods in their Vanadis® NIPT Assay and cfDNA Kits without a license, generating hundreds of millions of dollars in revenue.

## COUNT I

### Infringement Of The '277 Patent

85. Ravgen incorporates by reference paragraphs 1-84.

86. The '277 Patent is valid and enforceable.

87. Defendants have infringed, and continue to infringe, one or more claims of the '277 Patent under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, selling, and/or offering for sale in the United States, and/or importing into the United States, products and/or methods encompassed by those claims, including the Vanadis® NIPT Assay, the chemagic™ cfDNA 5k Kits, the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits.

88. For example, Defendants infringe at least exemplary claim 81 of the '277 Patent by making, using, offering to sell, and/or selling the Vanadis® NIPT Assay. For example, use of the Vanadis® NIPT Assay requires a method for preparing a sample for analysis, wherein said method comprises:

a. isolating free fetal nucleic acid (such as cell-free fetal DNA) from a sample (such as a maternal blood sample) (*see, e.g.*, Ex. 46 (describing extraction of cell-free fetal DNA from maternal blood sample using the Vanadis Extract® platform));

b. wherein said sample comprises an agent that inhibits lysis of cells, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor (such as Streck Cell-free DNA BCT® tubes containing maternal blood) (*see, e.g.*, *id*. (describing that the Vanadis® NIPT Assay uses samples of maternal blood collected in Streck Cell-free DNA BCT® tubes); Ex. 47 at 2 (describing Streck Cell-free DNA BCT® tubes as containing a "unique preservative [which] limits the release of genomic DNA, allowing isolation of high-quality cell-free DNA" and "specialized chemistry" that "***limit[s] cell lysis***")).

89. For example, Defendants infringe at least exemplary claim 81 of the '277 Patent by making, using, offering to sell, and/or selling the cfDNA Kits. For example, use of the cfDNA Kits includes a method for preparing a sample for analysis, wherein said method comprises:

a. isolating free fetal nucleic acid (such as cell-free fetal DNA) from a sample (such as a maternal blood sample) (*see, e.g.*, Ex. 55 (describing isolation of fetal-derived cell-free DNA from maternal blood samples using the NextPrep-Mag™ cfDNA Automated Isolation Kit for processing by the NEXTflex® Cell-Free DNA-Seq Kit); Ex. 24 (describing the chemagic™ cfDNA 5k Kit for "[a]utomated isolation of cell-free tumor or fetal DNA from 3 - 5 ml plasma"));

b. wherein said sample comprises an agent that inhibits lysis of cells, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor (such as Streck Cell-free DNA BCT® tubes containing maternal blood) (*see, e.g.*, Ex. 11 at 4 ("The NextPrep-Mag™ cfDNA Automated Isolation Kit is designed for extraction of cell-free DNA

(cfDNA) from up to 5 mL of human plasma" from "blood collected in . . . Streck BCT® tubes"); Ex. 56 at 3 ("The [chemagic™ cfDNA 5k Kit H24] is designed for the use with human plasma samples derived from EDTA, citrate or Streck Cellfree DNA BCT® tubes."); Ex. 47 at 2 (describing Streck Cell-free DNA BCT® tubes as containing a "unique preservative [which] limits the release of genomic DNA, allowing isolation of high-quality cell-free DNA" and "specialized chemistry" that "***limit[s] cell lysis***")).

90. Defendants have infringed, and continue to infringe, one or more claims of the '277 Patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, by using the Vanadis® NIPT Assay and the cfDNA Kits.

91. Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '277 Patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '277 Patent by selling or otherwise supplying the Vanadis® NIPT Assay and the cfDNA Kits with the knowledge and intent that third parties will use the Vanadis® NIPT Assay and the cfDNA Kits supplied by Defendants to infringe the '277 Patent; and with the knowledge and intent to encourage and facilitate third party infringement through the dissemination of the Vanadis® NIPT Assay and the cfDNA Kits and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the Vanadis® NIPT Assay and the cfDNA Kits.

92. Defendants specifically intended and were aware that the ordinary and customary use of the Vanadis® NIPT Assay and the cfDNA Kits would infringe the '277 Patent. For example, Defendants sell and provide the Vanadis® NIPT Assay and the cfDNA Kits, which when used in

their ordinary and customary manner intended and instructed by Defendants, infringe one or more claims of the '277 Patent, including at least exemplary claim 81. Defendants further provide product manuals and other instructional materials that cause Defendants' customers and other third parties to operate the Vanadis® NIPT Assay and the cfDNA Kits for their ordinary and customary use. Defendants' customers and other third parties have directly infringed the '277 Patent, including at least exemplary claim 81, through the normal and customary use of the Vanadis® NIPT Assay and the cfDNA Kits. Defendants accordingly have induced and continue to induce Defendants' customers and other users of the Vanadis® NIPT Assay and the cfDNA Kits to use the Vanadis® NIPT Assay and the cfDNA Kits in their ordinary and customary way to infringe the '277 Patent, knowing, or at least being willfully blind to the fact, that such use constitutes infringement of the '277 Patent.

93. Defendants have contributed to the infringement by third parties, including Defendants' customers, and continue to contribute to infringement by third parties, of one or more claims of the '277 Patent under 35 U.S.C. § 271(c), by making, selling and/or offering for sale in the United States, and/or importing into the United States, the Vanadis® NIPT Assay and the cfDNA Kits, knowing that those products constitute a material part of the inventions of the '277 Patent, knowing that those products are especially made or adapted to infringe the '277 Patent, and knowing that those products are not staple articles of commerce suitable for substantial non-infringing use.

94. Defendants have had knowledge of and notice of the '277 Patent and its infringement since at least May 15, 2020, when Ravgen expressly informed PerkinElmer of the existence of the '277 Patent and of Defendants' infringement.

95. Defendants' infringement of the '277 Patent was, and continues to be, willful and deliberate since at least May 15, 2020.

96. Ravgen has been and continues to be damaged by Defendants' infringement of the '277 Patent, and will suffer irreparable injury unless the infringement is enjoined by this Court.

97. Defendants' conduct in infringing the '277 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

## COUNT II

### Infringement Of The '720 Patent

98. Ravgen incorporates by reference paragraphs 1-97.

99. The '720 Patent is valid and enforceable.

100. Defendants have infringed, and continue to infringe, one or more claims of the '720 Patent under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, selling, and/or offering for sale in the United States, and/or importing into the United States, products and/or methods encompassed by those claims, including the Vanadis® NIPT Assay, the chemagic™ cfDNA 5k Kits, the NextPrep-Mag™ cfDNA Automated Isolation Kits, and the NEXTflex® Cell-Free DNA-Seq Kits.

101. For example, Defendants infringe at least exemplary claim 1 of the '720 Patent by making, using, offering to sell, and/or selling the Vanadis® NIPT Assay. For example, use of the Vanadis® NIPT Assay requires a method for detecting a free nucleic acid, wherein said method comprises:

a. isolating free nucleic acid (such as cell-free fetal DNA) from a non-cellular fraction of a sample (such as a maternal blood sample) (*see, e.g.*, Ex. 46 (describing

extraction of cell-free fetal DNA from maternal blood sample using the Vanadis Extract® platform));

b. wherein said sample comprises an agent that impedes cell lysis, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor (such as Streck Cell-free DNA BCT® tubes containing maternal blood) (*see, e.g.*, *id*. (describing that the Vanadis® NIPT Assay uses samples of maternal blood collected in Streck Cell-free DNA BCT® tubes); Ex. 47 at 2 (describing Streck Cell-free DNA BCT® tubes as containing a "unique preservative [which] limits the release of genomic DNA, allowing isolation of high-quality cell-free DNA" and "specialized chemistry" that "***limit[s] cell lysis***"));

c. detecting the presence or absence of the free nucleic acid (*see, e.g.*, Ex. 46 (describing detection of cell-free fetal DNA using probes specific to particular loci on chromosomes of interest, labeling them with fluorophores, and counting and analyzing the signals); Ex. 17 (same)).

102. For example, Defendants infringe at least exemplary claim 1 of the '720 Patent by making, using, offering to sell, and/or selling the cfDNA Kits. For example, use of the cfDNA Kits includes a method for detecting a free nucleic acid, wherein said method comprises:

a. isolating free nucleic acid (such as cell-free DNA) from a non-cellular fraction of a sample (such as a plasma sample) (*see, e.g.*, Ex. 55 (describing isolation of fetal-derived cell-free DNA from maternal blood samples using the NextPrep-Mag™ cfDNA Automated Isolation Kit for processing by the NEXTflex® Cell-Free DNA-

Seq Kit); Ex. 24 (describing the chemagic™ cfDNA 5k Kit for "[a]utomated isolation of cell-free tumor or fetal DNA from 3 - 5 ml plasma"));

b. wherein said sample comprises an agent that impedes cell lysis, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor (such as Streck Cell-free DNA BCT® tubes containing blood) (*see, e.g.*, Ex. 11 at 4 ("The NextPrep-Mag™ cfDNA Automated Isolation Kit is designed for extraction of cell-free DNA (cfDNA) from up to 5 mL of human plasma" from "blood collected in . . . Streck BCT® tubes"); Ex. 56 at 3 ("The [chemagic™ cfDNA 5k Kit H24] is designed for the use with human plasma samples derived from EDTA, citrate or Streck Cellfree DNA BCT® tubes."); Ex. 47 at 2 (describing Streck Cell-free DNA BCT® tubes as containing a "unique preservative [which] limits the release of genomic DNA, allowing isolation of high-quality cell-free DNA" and "specialized chemistry" that "***limit[s] cell lysis***"));

c. detecting the presence or absence of the free nucleic acid (*see, e.g.*, Ex. 57 at 15 (instructing users of the NEXTflex® Cell-Free DNA-Seq Kit to "[e]xamine library by electrophoresis to ensure proper library sizing and to verify exclusion of contaminating small and large fragments (recommended: LabChip® GXII Touch™ HT instrument (PerkinElmer®)."); Ex. 53 (describing that the NEXTflex® Cell-Free DNA-Seq Kit produces libraries from the extracted cell-free DNA for sequencing)).

103. Defendants have infringed, and continue to infringe, one or more claims of the '720 Patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, by using the Vanadis® NIPT Assay and the cfDNA Kits.

104. Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '720 Patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '720 Patent by selling or otherwise supplying the Vanadis® NIPT Assay and the cfDNA Kits with the knowledge and intent that third parties will use the Vanadis® NIPT Assay and the cfDNA Kits supplied by Defendants to infringe the '720 Patent; and with the knowledge and intent to encourage and facilitate third party infringement through the dissemination of the Vanadis® NIPT Assay and the cfDNA Kits and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the Vanadis® NIPT Assay and the cfDNA Kits.

105. Defendants specifically intended and were aware that the ordinary and customary use of the Vanadis® NIPT Assay and the cfDNA Kits would infringe the '720 Patent. For example, Defendants sell and provide the Vanadis® NIPT Assay and the cfDNA Kits, which when used in their ordinary and customary manner intended and instructed by Defendants, infringe one or more claims of the '720 Patent, including at least exemplary claim 1. Defendants further provide product manuals and other instructional materials that cause Defendants' customers and other third parties to operate the Vanadis® NIPT Assay and the cfDNA Kits for their ordinary and customary use. Defendants' customers and other third parties have directly infringed the '720 Patent, including at least exemplary claim 1, through the normal and customary use of the Vanadis® NIPT Assay and the cfDNA Kits. Defendants accordingly have induced and continue to induce Defendants' customers and other users of the Vanadis® NIPT Assay and the cfDNA Kits to use the Vanadis® NIPT Assay and the cfDNA Kits in their ordinary and customary way to infringe the '720 Patent,

knowing, or at least being willfully blind to the fact, that such use constitutes infringement of the '720 Patent.

106. Defendants have contributed to the infringement by third parties, including Defendants' customers, and continue to contribute to infringement by third parties, of one or more claims of the '720 Patent under 35 U.S.C. § 271(c), by making, selling and/or offering for sale in the United States, and/or importing into the United States, the Vanadis® NIPT Assay and the cfDNA Kits, knowing that those products constitute a material part of the inventions of the '720 Patent, knowing that those products are especially made or adapted to infringe the '720 Patent, and knowing that those products are not staple articles of commerce suitable for substantial non-infringing use.

107. Defendants have had knowledge of and notice of the '720 Patent and its infringement since at least May 15, 2020, when Ravgen expressly informed PerkinElmer of the existence of the '720 Patent and of Defendants' infringement.

108. Defendants' infringement of the '720 Patent was, and continues to be, willful and deliberate since at least May 15, 2020.

109. Ravgen has been and continues to be damaged by Defendants' infringement of the '720 Patent, and will suffer irreparable injury unless the infringement is enjoined by this Court.

110. Defendants' conduct in infringing the '720 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

## PRAYER FOR RELIEF

WHEREFORE, Ravgen prays for judgment as follows:

A. That Defendants have infringed each of the Patents-in-Suit;

B. That Defendants' infringement of each of the Patents-in-Suit has been willful;

C. That Ravgen be awarded all damages adequate to compensate it for Defendants' past infringement and any continuing or future infringement of the Patents-in-Suit up until the date such judgment is entered, including pre- and post-judgment interest, costs, and disbursements as justified under 35 U.S.C. § 284;

D. That any award of damages be enhanced under 35 U.S.C. § 284 as result of Defendants' willful infringement;

E. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that Ravgen be awarded the attorney fees, costs, and expenses incurred in connection with this action;

F. That Ravgen be awarded either a permanent injunction, or, at least, a compulsory ongoing licensing fee; and

F. That Ravgen be awarded such other and further relief at law or equity as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff Ravgen hereby demands a trial by jury on all issues so triable.

Dated: June 1, 2020

Respectfully submitted,

*/s/ Deron R. Dacus*

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